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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,069	03/30/2001	Kenneth T. Wheeler	9151-6	8239

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/823,069	WHEELER ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 8/3/04 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: ____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1,4-7,11,33 and 34*.

   Claim(s) withdrawn from consideration: *9,10 and 12-32*.

8. ☒ The drawing correction filed on *20 July 2001* is a)☒ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____

10. ☐ Other: _____

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Continuation of 2. NOTE: Amended claim 1 would require a new search. Amended claim 1 aslo raises new 35USC 112, first and second paragraph issues. Applicants arguments do not overcpme the rejection of record.The $\sigma 1\beta$ receptor of instant invention is expressed in a wide variety of tissues, normal and cancerous. Further, based on the art and the disclosure, the functionality of claimed $\sigma 1\beta$ receptor of SEQ ID NO: 2 is unknown. Members of the $\sigma 1$ receptor family are also highly divergent in their effects and ligand specificity. Based on the homology data of the $\sigma 1$ receptor family and the general classification into the superfamily of $\sigma 1$ receptor family, the specification discloses the claimed $\sigma 1\beta$ receptor is useful for detecting, preventing and/or treating diseases associated with cancer. There is no clear nexus between the treatable diseases/disorders and use of claimed $\sigma 1\beta$ receptor. Even if a test compound in an assay for drug screening affects the expression of Applicant's individual $\sigma 1\beta$ receptor, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. The ratio of $\sigma 1$ to $\sigma 1\beta$ density that may be an indicator of proliferate state of the cells is not disclosed. Even if the ratio of $\sigma 1$ to $\sigma 1\beta$ density varies in cells, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. There is no disclosure of the ratios of $\sigma 1$ to $\sigma 1\beta$ that would indicate proliferate state. For example, if the ratio of $\sigma 1$ to $\sigma 1\beta$ is 2:1, 1:2, 1.1:1 or 1:1.1, what is the interpretation for the result? None is provided. Given this consideration, and those stated in the previous Office Action. The method of using $\sigma 1\beta$ receptor has no well-established use. The artisan is required to perform further experimentation on the claimed $\sigma 1\beta$ receptor itself in order to determine to what use any information regarding this protein could be put.

Further the specifcication is still not in sequence compliance (see subsection 2 of prevoius Office Actioon)

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